

**Notice of Allowability**

Application No.

10/594,266

Examiner

JAE W. LEE

Applicant(s)

ICHINOSE ET AL.

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02/04/2011.
2. ☒ The allowed claim(s) is/are 15, 16 and 42.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>02/04/2011</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                     | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

### **NOTICE OF ALLOWANCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/2011 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 02/04/2011 was filed after the mailing date of the Notice of Allowance on 11/10/2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, all of the references cited therein have been considered by the examiner. It is noted by the Examiner that the newly disclosed references do not affect the patentability of the previously allowed claims.

### **REASONS FOR ALLOWANCE**

The following is an Examiner's statement of reasons for allowance. While Russell et al. (Cholesterol 25-Hydroxylase, WO 2000/23596, published on 04/27/2000, see IDS) specifically teaches a method of screening for an agent that modulates the interaction of human cholesterol 25-hydroxylase polypeptide as set forth in SEQ ID NO: 2 (which is identical to Applicant's SEQ ID NO: 2, see below sequence alignment from

SCORE 20091211\_121822\_us-10-594-266-2.rag), to a binding target, said method comprising the steps of: incubating a mixture comprising said polypeptide, a binding target of said polypeptide, and a candidate agent; detecting the binding affinity of said polypeptide to said binding target to determine an agent-biased affinity, wherein a difference between the agent-biased affinity and the reference affinity indicates that said agent modulates the binding of said polypeptide to said binding target, the Examiner has found no teaching or suggestion in the prior art directed to a method of screening for a potential prophylactic/therapeutic agent for *respiratory diseases*, which comprises: (i) culturing a cell expressing a protein in the presence and absence of a test compound and measuring cholesterol hydroxylation activity of the protein, wherein the protein comprises (a) the amino acid sequence of SEQ ID NO: 2 or (b) an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 2 and having cholesterol hydroxylation activity, or a salt thereof; (ii) comparing the measured cholesterol hydroxylation activity of the protein in the presence of the test compound with the measured activity of the protein in the absence of the test compound; (iii) selecting the test compound which decreases cholesterol hydroxylation activity of the protein by at least 20%; (iv) *measuring and comparing the production of inflammatory cytokines in the presence and absence of the test compound selected in step (iii); and (v) selecting the test compound which decreases the production of inflammatory cytokines as the prophylactic/therapeutic agent for respiratory diseases* (italicized for added emphasis). Therefore, the claimed invention is novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAE W. LEE whose telephone number is (571)272-9949. The examiner can normally be reached between 9:00 to 5:30 on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/  
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/  
Primary Examiner, Art Unit 1656